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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,058	10/17/2003	Kathryn F. Sykes	UTSD:872US/10313410	9509
32425 7590 10/02/2007 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 10/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10688058	10/17/03	SYKES ET AL.	UTSD:872US/10313410

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EXAMINER

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ART UNIT	PAPER
1645	100107

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/688,058
Filing Date: October 17, 2003
Appellant(s): SYKES ET AL.

Travis M. Wohlers
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 29 June 2007 appealing from the Office action mailed 25 September 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO98/59071

Choi

30 September 1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

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1. Claims 48 and 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al (WO98/59071, Dec. 1998).

The claims are drawn to a vaccine composition comprising at least one (claims 31, 32, 34, 44, and 48), or at least two (claims 45 and 49) or at least three (claims 46 and 50) or at least four (claims 47 and 51) different *Borrelia* antigens or fragments thereof in a pharmaceutically acceptable carrier.

Choi et al teach the claimed vaccine composition combinations by teaching a vaccine composition comprising at least one or more *B. burgdorferi* polypeptides selected from a group consisting of four different peptide constructs (claim 16) in a pharmaceutically acceptable carrier. One of the whole peptides from which the constructs are formed, listed in Table 1 (f810.aa; page 134), is identical to the instantly claimed SEQ ID NO:8, and comprises a fragment of instantly claimed SEQ ID NO:6. Another whole peptide from which the constructs are formed as taught by Choi et al (f229.aa; page 169) is 98.2% identical to the instantly claimed SEQ ID NO:12.

2. Claims 48 and 88-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 48 is drawn to a nonelected invention, i.e., "a vaccine composition comprising a first polynucleotide". Claims newly added claims 88-91 depend from claim 48, but do not clarify the invention.

(10) Response to Argument

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Rejection 1. Appellant argues that while Choi et al discloses hundreds of sequences reportedly obtained from *B. burgdorferi* (see Table 1 on pages 56 to 215), it fails to disclose a single example where even one of these sequences was used to elicit an immune response in an animal. Choi has done nothing more than venture a guess that one or more of the hundreds of *B. Burgdorferi* genes or gene fragments that were sequenced and listed in the specification would be useful antigens in a vaccine (Choi, p. 37, ln. 5, to p. 38, ln. 19). In order to obtain Appellant's claimed vaccine composition from Choi, a person of ordinary skill in the art would have to analyze an enormous number of *Borrellia* sequences.

In contrast to the lack of guidance in the Choi et al disclosure as to which *Borrellia* sequences may be effective antigens in a vaccine, Appellant's specification demonstrated that vaccinating mice with the *Borrellia* antigens encompassed by the current claims provided protection from challenge with subcutaneously injected *B. burgdorferi* spirochetes as assayed by tibiotarsel joint diameter measurements and spirochete densities (see e.g., p. 88, ln. 15-29). Specifically, the SEQ ID NOs recited in current claim 48 are also identified in Table 2 of the specification (p. 89- 94) as corresponding to the fragments and full-length coding regions of 34 clones identified in the second round of array analysis at the intersections of positive groups based on inflammation data or spirochete density data (p. 89, ln. 12-18). The disclosure in Choi is insufficient to enable the presently claimed vaccine, particularly given the art-recognized challenges associated with identifying *Borrellia* antigens that are effective at eliciting an immune response and do not induce an autoimmune reaction in the host. A claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled.

The examiner has considered appellant's argument, but does not find it persuasive. The instant claims are drawn to a product, i.e., compositions comprising antigen(s) from *Borrellia*,

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wherein said antigens comprising various SEQ ID NOs. Choi et al teaches how to make the required antigens and compositions thereof. Therefore, Choi et al is enabled for the production of the claimed compositions. Utilizing the compositions as vaccine compositions is an intended use of the product, and does not place any structural characteristics onto the claimed antigens that are not taught by Choi et al following their teachings on how to make the antigen compositions.

Rejection 2. Appellant argues that the rejection is improper because the amendment of claim 48 merely involved re-writing the claim in independent form because claim 48 was included in the Group II invention of the Restriction Requirement.

The examiner has considered appellant's argument, but does not find it persuasive because the claims remain being to two different inventions. One invention is that which was elected, while the second invention is the nonelected invention drawn to polynucleotides.


(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Rodney P. Swartz, Ph.D., Primary Examiner, AU 645


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